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WILEY REIN LLP
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EXAMINER

LONG, SCOTT

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Please find below and/or attached an Office communication concerning this application or proceeding.

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WASHINGTON DC 20006

In re Application of:

Carillo et al.

Serial No.: 10/788,489

Filed: March 1, 2004

Attorney Docket No.: **ST94037B**

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: PETITION DECISION
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This is in response to the petition under 37 CFR § 1.181, filed January 26, 2009, requesting that either the finality of the Office action of April 30, 2008 be withdrawn or that applicants' amendment filed under 37 CFR 1.116 after final Office action on October 30, 2008 be entered, thus overturning the examiner's decision to not enter said amendments as communicated in the Advisory Action mailed November 26, 2008.

BACKGROUND

The examiner mailed a non-final Office action on August 17, 2007 setting a three month statutory limit for reply. At the time of this non-final Office action, claims 1-8 were pending and examined on their merits. *Inter alia*, the examiner rejected claims 2 and 5-7 under 35 U.S.C. § 112, second paragraph, for reciting indefinite matter, rejected claims 5 and 7 under 35 U.S.C. § 112, first paragraph, for lacking written description, rejected claims 1-2 and 8 under 35 U.S.C. 102(b) as being anticipated by Ramsby et al. (1994) and rejected claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Ramsby et al. (1994) in view of Asada et al. (1989).

In response to the non-final Office action of August 17, 2007, applicants filed a response on February 19, 2008. Said response included an amendment to claims 1, 2 and 5.

The examiner mailed a final Office action on April 30, 2008 setting a three month statutory limit for reply. At the time of this final Office action, claims 1-8 remained pending in the application and were examined on their merits. *Inter alia*, the examiner withdrew the rejection made previously over claims 2 and 5-7 under 35 U.S.C. § 112, second paragraph, for reciting indefinite matter, withdrew the rejections made over claims 5 and 7 under 35 U.S.C. § 112, first paragraph, for lacking written description, withdrew the rejection of claims 1-2 and 8 under 35 U.S.C.

102(b) as being anticipated by Ramsby et al. (1994) and removed the rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Ramsby et al. (1994) in view of Asada et al. (1989). The examiner instituted a new rejection of claims 1-8 under U.S.C. 103(a) as being unpatentable over Henkart et al. (US-5,607,831) in view of Squier et al. (Journal of Cellular Physiology, May 1994; 159(2): 229-237) and further in view of Maki et al. (The Journal of Biological Chemistry, Nov.15, 1989; 264(32): 18866-18869) and further in view of Haake et al. (J Invest Dermatol, 1993; 101 : 107-112).

Applicants filed a Notice of Appeal on October 30, 2008.

In response to the final Office action issued April 30, 2008, applicants submitted a response under 37 CFR 1.116 after final Office action which included remarks, arguments and a proposed amendment to claim 1. Applicants' proposed amendment reads as follows:

1. (Currently amended) A method for detecting an inhibitor of p53 protein degradation comprising providing a cell extract containing one or more p53 proteins and one or more proteases, administering a peptide or protein inhibitor of calpain protease activity to the cell extract, and measuring p53 protein and p53 protein fragments.

On November 26, 2008, the examiner mailed an Advisory Action. In this Advisory Action, the examiner indicated that applicants' proposed claim amendments submitted on April 30, 2008 under 37 CFR 1.116 after final Office action would not be entered because they raised the issue of further consideration and/or search. The examiner specifically indicated:

The applicant has argued (Remarks, page 5 bridging page 6, filed 10/30/2008) that the examiner's claim interpretation is "nonsensical." The applicant further states, "applicant's have amended claim 1 to fully clarify that the peptide or protein inhibitor of calpain protease activity is administered to the cell extract." (Remarks, page 6, lines 19-21). Since the disputed claim interpretation has been amended to further limit the claims, the examiner believes this would require further search and consideration. Accordingly, the proposed amendments will not be entered.

In response thereto, applicants filed this petition under 37 CFR § 1.181 on January 26, 2009, requesting that either the finality of the Office action of April 30, 2008 be withdrawn or that applicants' amendment filed under 37 CFR 1.116 after final Office action on October 30, 2008 be entered, thus overturning the examiner's decision to not enter said amendments as communicated in the Advisory Action mailed November 26, 2008.

It is noted that applicants' Petition to remove the finality of the final Office action of April 30, 2008 is untimely as applicants are provided 2 months to Petition from the date of mailing of the petitionable Office action (37 CFR § 1.181(f)). Nonetheless, a decision on the finality of the April 30, 2008 final Office action has been rendered herein.

DISCUSSION

In the petition filed on January 26, 2009, applicants first argue that rendering final the Office action mailed April 30, 2008 was improper due to the examiner's new rejection therein of

claims 1-8 under U.S.C. 103(a) as being unpatentable over Henkart et al. (US-5,607,831) in view of Squier et al. (Journal of Cellular Physiology, May 1994; 159(2): 229-237) and further in view of Maki et al. (The Journal of Biological Chemistry, Nov.15, 1989; 264(32): 18866-18869) and further in view of Haake et al. (J Invest Dermatol, 1993; 101 : 107-112).

Applicants specifically argue that the new ground of rejection instituted by the examiner in the final Office action was not necessitated by applicants' amendment to the claims:

All of these alleged "limitations" were present in the original, unamended claims. More specifically, claim 2 has always disclosed that the inhibitor is a calpastatin, meaning that the Henkart, Squier, and Maki references could have been cited in the initial Office Action. Additionally, independent claim 1 has always disclosed "providing a cell extract containing one or more p53 proteins," meaning that Haake and Ramsby could have been cited in the initial Office Action.

Applicants' argument that the 35 USC § 103 rejection rendered in the final Office action is a *new* rejection is persuasive since the 35 USC § 103 rejection was not previously set forth on the record by the examiner. It is noted that new rejections in a final Office action are permitted under certain circumstances. Specifically, finality of Office actions on a second action is governed by MPEP § 706.07(a):

Under present practice, second or any subsequent actions on the merits shall be final, *except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).* Where information is submitted in an information disclosure statement during the period set forth in 37 CFR 1.97(c) with a fee, the examiner may use the information submitted, e.g., a printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. (emphasis added)

Therefore, the MPEP establishes that new rejections may be made in final Office actions so long as the new rejections are necessitated by applicants' amendment(s) to the claims, or based upon information submitted in an information disclosure statement. Additionally, MPEP § 706.07(a) states: "Furthermore, a second or any subsequent action on the merits in any application or patent undergoing reexamination proceedings *will not be made final if it includes a rejection, on newly cited art, other than information submitted in an information statement filed under 37 CFR 1.97(c)...of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art.*" (emphasis added)

An analysis of the nature of the claim amendments made by applicants prior to the final Office action is in order: the complete set of claims, as they were amended by applicants on February 19, 2008 are set forth *infra*:

1. (Currently Amended) A method for detecting an inhibitor of p53 protein degradation comprising providing a cell extract containing one or more p53 proteins and one or more proteases, administering an a peptide or protein inhibitor of calpain protease activity, and measuring p53 protein and p53 protein fragments.

2. (Currently Amended) The method of claim 1, wherein the inhibitor administered is a calpastatin.
3. (Original) The method of claim 2, wherein the calpastatin is encoded by one of SEQ ID NO: 1-3.
4. (Original) The method of claim 1, wherein the cell extract is derived from a tumor cell.
5. (Original) The method of claim 1, wherein the inhibitor administered is a fragment of calpastatin.
6. (Original) The method of claim 4, wherein the inhibitor is a calpastatin.
7. (Original) The method of claim 4, wherein the inhibitor is a fragment of calpastatin.
8. (Original) The method of claim 1, wherein measuring the p53 protein and p53 protein fragments is performed using gel electrophoresis.

It is evident that applicants' amendment to claim 1 limited the 'inhibitor' to more narrowly recite 'a peptide or protein.' Applicants' amendment to claim 2 which inserted 'administered' prior to 'is a calpastatin' which resulted in the limitation '...wherein the inhibitor administered is a calpastatin' is not deemed to limit nor broaden the scope of claim 2 because claim 1 states 'administering an inhibitor of calpain protease activity.' Because claim 2 is dependent upon claim 1, the only necessary conclusion which can be made is that 'the inhibitor' of claim 2 is 'the inhibitor' of claim 1 which is 'administered.' The amendment to claim 5 whereby applicants inserted 'administered' following 'inhibitor' also is not deemed to limit claim 5 any more than it originally stated. Thus, the amendments made to claims 2 and 5 were merely claim amendments to the matter of form and not substance.

It is further evident from said amendment, that prior to said amendment and therefore at the time the non-final Office action was mailed; claims 2-3 limited claim 1 to wherein the inhibitor was calpastatin and further limited claim 1 to wherein the calpastatin was encoded by one of SEQ ID NO: 1-3, respectively, claim 5 limited claim 1 to wherein the inhibitor was a fragment of calpastatin, claim 6 limited claim 4 to wherein the inhibitor was calpastatin, and claim 7 limited claim 4 to wherein the inhibitor was a fragment of calpastatin. Therefore, all of claims 2-3, 5, 6 and 7 were already respectively limited to wherein the inhibitor was a protein or peptide and applicants' amendment to claims 1, 2 and 5 of February 19, 2008 did not change the scope of any of claims 2, 3, 5, 6 or 7.

Thus, it can be said that the only claims which were actually narrowed by applicant in said amendment submitted after final Office action were claims 1, 4 and 8. Subsequently, *any new rejection instituted over any claims other than claims 1, 4 and 8 in the final Office action could not have been necessitated by applicants' amendments to the claims.* On this account, it is clear that the rejection of claims 2, 3, 5, 6 and 7 under U.S.C. 103(a) as being unpatentable over Henkart et al. (US-5,607,831) in view of Squier et al. (Journal of Cellular Physiology, May 1994; 159(2): 229-237) and further in view of Maki et al. (The Journal of Biological Chemistry, Nov.15, 1989; 264(32): 18866-18869) and further in view of Haake et al. (J Invest Dermatol, 1993; 101 : 107-112) was indeed a new rejection instituted by the examiner in the final Office action which was not necessitated by applicants' amendment to these claims, nor necessitated by

the filing of an IDS in the interim between the mailing of the non-final Office action and the final Office action.

Hence, applicants' arguments are well-taken that the finality of the Office action issued April 30, 2008 was premature and thus improper. The finality of said Office action is herein REMOVED.

Applicants' second argument contends that the examiner erred in refusing to enter the amendment filed under 37 CFR 1.116 after final Office action on October 30, 2008. Applicants assert that the amendment merely placed claim 1 in better condition for appeal and consequently, should be entered. To reiterate, applicants' proposed amendment read as follows:

1. (Currently amended) A method for detecting an inhibitor of p53 protein degradation comprising providing a cell extract containing one or more p53 proteins and one or more proteases, administering a peptide or protein inhibitor of calpain protease activity to the cell extract, and measuring p53 protein and p53 protein fragments.

Prosecution after final rejection is governed by 37 C.F.R. § 1.116 which states, in part:

(b) After a final rejection or other final action (§ 1.113) in an application or in an ex parte reexamination filed under § 1.510, or an action closing prosecution (§ 1.949) in an inter partes reexamination filed under § 1.913, but before or on the same date of filing an appeal (§ 41.31 or § 41.61 of this title):

- (1) An amendment may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action;
- (2) An amendment presenting rejected claims in better form for consideration on appeal may be admitted; or
- (3) An amendment touching the merits of the application or patent under reexamination may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented.

The examiner indicated on the Advisory Action form PTOL-303 that the proposed amendments filed after final rejection would not be entered because they raised new issues that would have required further consideration and/or search. The examiner, on the addendum page of the Advisory Action form clearly indicated:

The applicant has argued (Remarks, page 5 bridging page 6, filed 10/30/2008) that the examiner's claim interpretation is "nonsensical." The applicant further states, "applicant's have amended claim 1 to fully clarify that the peptide or protein inhibitor of calpain protease activity is administered to the cell extract." (Remarks, page 6, lines 19-21). Since the disputed claim interpretation has been **amended to further limit** the claims, the examiner believes this **would require further search and consideration**. Accordingly, the proposed amendments will not be entered. (emphasis added)

Hence, the examiner properly reasoned that applicants' amendment to claim 1 which inserted 'to the cell extract' would require a new search and consideration due to the fact that 'to the cell extract' served to limit the claimed invention. Furthermore, while applicants argue that the limitation 'to the cell extract' merely places the claim in better form for appeal; this argument is not accepted. MPEP § 714.13 II and III offer further insight as to whether a claim amendment filed after final Office action places the claim(s) in better condition for allowance.

MPEP § 714.13 II indicates:

Except where an amendment merely cancels claims, adopts examiner suggestions, removes issues for appeal, or in some other way requires only a cursory review by the examiner, compliance with the requirement of a showing under 73 CFR 1.116(b)(3) is expected in all amendments after final rejection.

MPEP § 714.13 III (A) indicates, in part:

(A) The claims, if amended as proposed, would not avoid any of the rejections set forth in the last Office action, and thus the amendment would not place the case in condition for allowance or in better condition for appeal.

‘[R]emoves issues for appeal’ as stated by MPEP § 714.13 II means ‘issues of record.’ There was no ‘issue’ on record regarding the breadth of the claim(s) prior to the proposed amendment filed by applicants after final Office action which proposed to insert the limitation ‘to the cell extract.’ It is therefore decided that the proposed added limitation ‘to the cell extract’ does not ‘avoid any of the rejections set forth in the last Office action’ because the proposed insertion of ‘to the cell extract’ was not suggested by the examiner and consideration of such an amendment would require more than a cursory review by the examiner in order to ascertain whether or not the limitation would serve to overcome the outstanding rejections to the claimed invention.

Hence, no impropriety can be found on the part of the examiner for refusing to admit applicants’ proposed amendments filed under 37 CFR 1.116 after final Office action on October 30, 2008.

However, notwithstanding the decision that the examiner’s refusal to enter the after final amendment was indeed proper, applicants’ request to enter the claim amendment is granted based upon the conclusion rendered herein; that the finality of the Office action instituted by the examiner on April 30, 2008 was improper and is herein removed. Due to removal of finality, the amendment filed on October 30, 2008 will be entered and treated as an amendment filed under 37 CFR § 1.111; or in other words, treated as an amendment filed prior to a final Office action.

Accordingly, upon careful review of the prosecution history of this case, applicants’ arguments are found persuasive. Consequently, the finality of the Office action mailed April 30, 2008 is hereby REMOVED. The amendment submitted by applicants after final Office action on October 30, 2008 is hereby ENTERED, whereby said amendment will be treated as an amendment filed under 37 CFR § 1.111 and acted on accordingly by the examiner.

DECISION

The petition is **GRANTED**.

This case will be forwarded to the examiner to take action not inconsistent with this decision.

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.

Andrew Wang
Acting Director, Technology Center 1600

A handwritten signature in black ink, appearing to be 'Andrew Wang', written over the printed name.